Cwm Taf Morgannwg University Health Board

Maternity and Neonatal Services Serious Incidents Assurance Review & Board Systems and Processes for Reporting, Management and Review of Patient Safety Incidents

May 2022

Final 1.0 16 May 2022

EXECUTIVE SUMMARY

Maternity and Neonatal Serious Incidents Assurance Review

The Royal College of Obstetricians and Gynaecologists (RCOG) and the Royal College of Midwives (RCM) report into the Maternity and Neonatal Services, within Cwm Taf Morgannwg University Health Board (CTMUHB), identified a number of areas for improvement and action. One of the recommendations related to the oversight, identification, investigation and learning from patient safety incidents. Despite the Health Board having made some progress in this area, the Independent Maternity Services Oversight Panel (IMSOP) remained insufficiently assured. As a result, IMSOP commissioned the NHS Wales Delivery Unit Quality and Safety Team (DUQST) to undertake an assurance review to:

- To identify and support improvements to the systems and processes for the identification, management, investigation and learning from serious incidents identified in the recommendations of the RCOG/RCM report.

- Progress to closure the post October 2018 backlog of 72 maternity and neonatal serious incidents.

This assurance review is now completed with Maternity, Neonatal and Corporate Quality and Safety (Q&S) teams having made significant strides towards RCOG/RCM recommendation, with their incident management now in a much stronger place. This has been achieved through strengthening the quality of the investigation process and governance arrangements, including, assurance, escalation and leadership.

As a result, the RCOG/RCM recommendations have been met with the appropriate levels of assurance in place across the recommendations to confirm this.

As a result of the assurance review and the renewed focus this placed on the post October 2018 open maternity and neonatal serious incidents, all 72 outstanding incidents have now been investigated and recommended for closure with learning identified along with appropriate improvement plans.

The DUQST is satisfied that the 72 investigations have been completed to an appropriate standard with the quality of them comparable with other health boards, some of the new practices implemented make a good benchmark for other health boards to measure themselves against.

Many of the improvements made to the incident investigation process are now being embedded as normal practice, which needs to continue.

There are also a number of residual legacy improvements that need to be seen through to completion, such as, the implementation of the national RL Datix Once for Wales Concerns Management System (RL Datix OfW CMS), expanding the MDT approach for investigations to include external independent expertise where appropriate, the neonatal team will benefit from this in particular as identified in the neonatal deep dive, the implementation of the new Q&S assurance and risk framework and the review existing polices and frameworks in line with the new national incident reporting policy. To maintain momentum, they need to be reflected in the CTMUHB.

These legacy improvement actions should be rolled forward into the CTMUHB milestone plane so that progress against their completion can be monitored through existing governance and oversight arrangements for the longer term maternity improvement plan.

It is also key that the new Maternity and Neonatal services improved management of care quality and patient safety is not lost in the current organisation restructure, it is recommended the Maternity Quality Assurance Framework helps to inform the new CTMUHB structure to ensure this does happen. It is also worth noting that during the construction of this report that Healthcare Inspectorate Wales have recently conducted a return visit to the Prince of Wales Hospital maternity service in March 2022 and the initial feedback is they found a positive culture with the team on a strong footing of improvement.

Whilst significant improvements have been made to meet the recommendations of both reviews the Maternity, Neonatal and Corporate Quality & Safety teams are on a continuous improvement journey. This is of particular note for the Neonatal team that are not as far down the journey of improvement having been included in the IMSOP clinical review

Targeted Intervention into Board Systems and Processes for Reporting, Management and Review of Patient Safety Incidents

Prior to the DU being commissioned to undertake an assurance review of maternity and neonatal serious incidents a targeted intervention into the broader systems and processes for reporting, managing and review of patient safety incidents and relevant concerns had been commissioned. Following the escalation of concerns the Welsh Government (WG) took the decision to place the CTMUHB maternity services into special measures, and the overall HB into targeted intervention in March 2019.

This intervention has suffered from a number of changes in personnel across both the CTMUHB and the DUQST, along with the disruption caused by the COVID 19 pandemic. During this targeted intervention there have been a number of reports published by the DUQST on the management of patient safety incidents and concerns, with the recommendations changing across these different reports, plus improvement actions plans by CTMUHB in response to those reviews. As a result, the current DUQST agreed for the CTMUHB corporate Quality and Safety team to undertake a self-assessment to the latest establish set of recommendations from previous reports that also aligned with the latest CTMUHB action plan. The self-assessment and supporting evidence was then assessed for assurance by the DUQST.

It was identified that the CTMUHB had made significant improvements to the governance of quality and safety, including the management of incident and concerns, risks and patient safety. This was also reflected in the May 2021 joint Audit Wales and Health Inspectorate Wales review of progress against recommendations following the original review into quality governance arrangements in CTMUHB (November 2019).

The Health Board is well placed to build on the improvements that have been put in place both for maternity/neonatal services and more broadly across its quality governance arrangements, in line with the recommendations of both the RCOG/RCM and joint Audit Wales and Health Inspectorate Wales recommendations.

Introduction

Following the discovery of the Health Board under-reporting a number of Serious Incident (SI) cases, the Welsh Government commissioned RCOG and RCM to undertake an independent external review. The review, which took place on 15-17th January 2019, analysed the care provided by the Health Board's Maternity Services.

As a result, the CTMUHB Maternity Services was placed into special measures, subsequently the then Health Minister established the Independent Maternity Services Oversight Panel (IMSOP) whose functions included undertaking a Clinical Review (CR) programme. One of overarching aims of the programme was to ensure "*the quality assurance of Serious Incident investigations that have occurred post 01 October 2018 is completed in order to validate the current ways of working as fit for purpose going forward*".

In addition to the maternity services being placed into special measures and the resulting review of the management of incidents and concerns the DU was also asked to undertake an intervention targeted at CTMUHB's wider systems and processes for reporting, management and review of patient safety incidents and relevant concerns. This intervention commenced on March 2019 and has been ongoing since.

Whilst the above identifies two distinct interventions that the DUQST are engaged in with CTMUHB there is significant cross over between them and as a result is has been agreed with Welsh Government to combine them into a single report. In order to maintain a level of separation between the two reviews the findings, progress made against recommendations and assurance levels have been split into two parts:

1. Part A - Maternity and Neonatal Services Serious Incidents Assurance Review

2. Part B – Intervention into Board Systems and Processes for Reporting, Management and Review of Patient Safety Incidents

Background

Prompting the DUQST involvement with the CTMUHB Maternity, Neonatal and Central Quality & Safety teams the IMSOP Clinical Review Team have not been sufficiently assured by the review of Maternity and Neonatal Serious Incidents and the processes in place, although it is acknowledged that significant improvements have been made. The IMSOP Clinical Review Team provided feedback to the Health Board in the form of "SBARs", which outline the concerns of and further improvements required. The concerns expressed by the IMSOP Clinical Review Team were exacerbated by the slow progress of adapting the governance of quality and safety at a corporate level. This resulted in the Welsh Government commissioning the DU to conduct an assurance review of the management of incidents within the Maternity and Neonatal teams along with the Corporate Quality & Safety team, Terms of Reference for the assurance review can be seen at appendix 1.

It should be noted that the COVID 19 pandemic has had an impact on the Health Boards capacity to effectively respond to the targeted intervention, IMSOP and the assurance review. This was due to the deployment of members of the Quality and Safety corporate team to clinical duties as part of the Health Boards response to the increased demand generated by the pandemic.

Methodology

The DUQST has undertaken the following in support of both the assurance review and the targeted intervention:

- Supporting the CTMUHB maternity, neonatal and corporate quality & safety teams to develop improved processes for the management of incidents in line with the National Reportable Incident Policy and implementation framework.
- Through regular meetings monitored progress against a defined trajectory to complete incident investigations and submit to the Welsh Government for closure.
- Undertaken observations of the newly developed incident assurance panels.
- Developed a self-assessment against the RCOG and targeted intervention recommendations for the CTMUHB teams to complete and provided feedback on gaps in assurance against achieving the recommendations.
- Conducted reviews of internal committee papers, reports and risk registers.
- Conducted a review of reports for external audits and inspections conducted by independent third parties, notably the joint review conducted Audit Wales and Health Inspectorate Wales into the quality governance arrangements (a summary of progress) in CTMUHB.

FINDINGS

1. Part A - Maternity and Neonatal Services Serious Incidents Assurance Review

Overall

Overall the Maternity, Neonatal and Corporate Quality & Safety teams have collaboratively taken ownership of the improvement actions required to meet the RCOG/RCM recommendations against the Royal Colleges Review Terms of Reference (ToR) 3 and the seven recommendations of the *Maternity and Neonatal Serious Incident Assurance Review* report, August 2021. They have also fully engaged with the DUQST when tasked with supporting the implementation of the required improvements. This has resulted in significant improvements to the management of incidents in the Maternity and Neonatal services and the governance arrangements required in support of service quality and safety.

Whilst significant improvements have been made to meet the recommendations of both reviews the Maternity, Neonatal and Corporate Quality & Safety teams are on a continuous improvement journey, with further improvements still being realised. This is of particular note for the Neonatal team that are not as far down the journey of improvement having been included in the IMSOP clinical review

process more latterly. That said they have embraced the necessary change and are maturing into the improved systems and processes for managing incidents.

Through the assurance review process, the DUQST have gained assurance across the key areas of improvements required by IMSOP, these are:

- **RCOC/RCM Recommendations against ToR 3** – Significant improvements have been made to the systems and processes the identification, management, investigation and learning from serious incidents, this has been achieved with direct oversight and support from the DUQST. This has led to a significant improvement in the quality of RCA's for serious incidents, including the identifications of lessons learnt and associated improvement action plans, were required there has been a multidisciplinary team (MDT) approach to the RCA's, incident assurance panels and feedback to women and families. Of particular note has been a more collaborative approach between the maternity and neonatal teams.

- **Serious Incident Backlog (Post Oct 2018)** - As a result of the Assurance Review and the renewed focus this placed on the significant number of open maternity and neonatal incidents, 72 in total, this backlog has been cleared with no outstanding legacy serious incident Root Cause Analysis (RCA) investigations remaining.

The DUQST is satisfied that the 72 investigations have been completed to an appropriate standard with quality of them comparable with other health boards with some of the new practices implemented a good benchmark for other health boards to measure themselves against. This now means the maternity and neonatal teams can focus on new incidents and transition the improvements as standard practice.

The improvements made to the management of incidents by the maternity and neonatal teams, in particular the use of MDT assurance panels to review the quality of the RCA's and the learning identified are now being shared across the Health Board as best practice by the corporate Quality & Safety team. It should also be noted that other health boards could learn from this good practice.

The DUQST is also assured that the seven recommendations made as part of the initial assurance review have now been fully met by the CTMUHB maternity and neonatal services. The assessment and associated assurance levels can be seen in table 1.

Although overall the DUQST is assured overall the RCOG/RCM recommendations have been met along with the seven recommendations of the DU initial review there are, however, some gaps in the assurance as a result legacy actions that are still to be completed:

1. The implementation of the new national RL Datix OfW CRM as part of the national roll out, including staff training in incident reporting and the use of RL Datix.

2. Increased use of external expertise to provided independent advice and support for serious incident investigations and identification of learning, the neonatal team will particularly benefit from this approach as part of their improvement journey. This is also a recommendation made in the neonatal deep dive report, whilst not part of the assurance review the DUQST team support this recommendation and the wider use of external expert advice and support. This is a role that the Maternity and Neonatal network could provide, using clinicians from the network or the identification of other clinicians.

3. The implementation of a Maternity and Neonatal Assurance Framework, currently awaiting approval and full implementation.

4. The current incident investigation policy and toolkit require a review and updating in line with the new national incident reporting policy and guidelines.

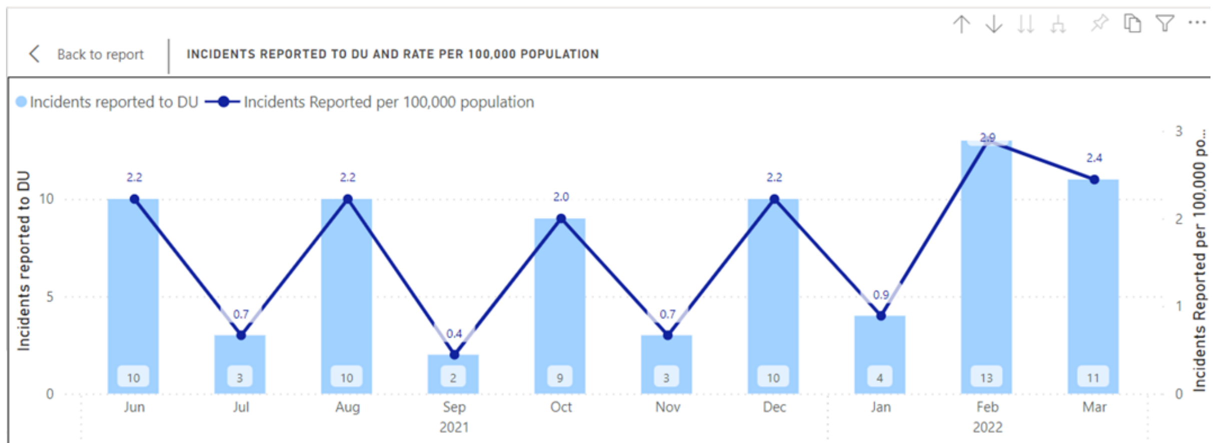
All of the above legacy actions will need to be rolled forward into the Health Board's milestone plan that sets out the next steps in the longer-term improvement programme. The benefit of this approach is there is already an existing delivery and oversight mechanism in place, provided by the Maternity and Neonatal Improvement Board, the CTMUHB Quality and safety Committee and IMSOP to help maintain continued focus and momentum.

A detailed analysis of evidence and levels of assurance against the recommendations from both the RCOG/RCM and DUQST initial assurance assessment can be seen in table 1.

The newly proposed changes to the Health Board structures that will include a Women and Children's directorate will serve to strengthen the governance arrangements supporting the maternity and neonatal teams across the Health Board, in particular the point of service delivery to Board flow of information, strengthening the assurance of high quality care and safe care. However, it is imperative that the improved management of care quality and patient safety is not lost in the current restructure, it is recommended the Maternity Quality Assurance Framework helps to inform the new CTMUHB structure to ensure this does happen.

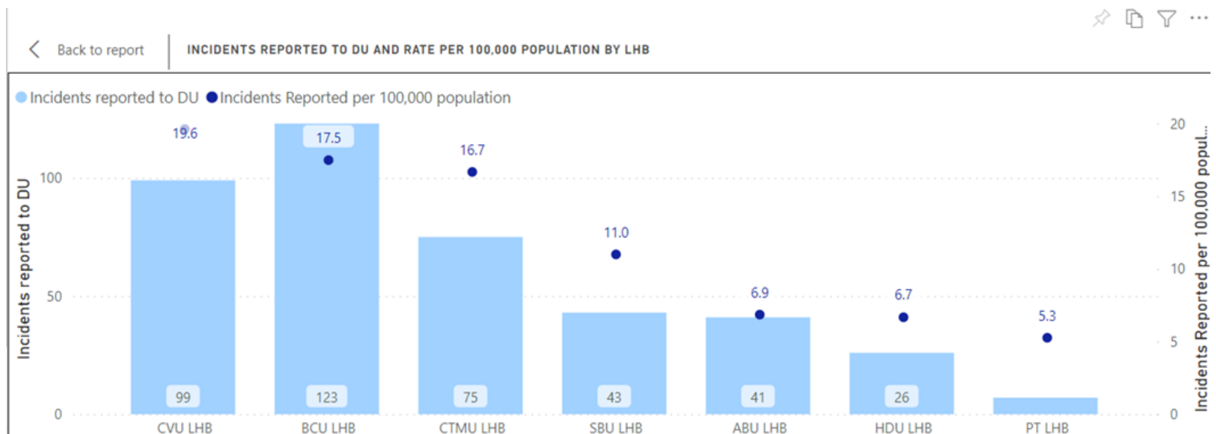
The Health Board has transitioned into adopting the National Incident policy for wales, with good evidence of Nationally reported incidents. As such both in the immediate and long term the DUQST will continue to monitor the quality of incidents that meet the threshold for national reporting, as part of the current national incident reporting policy and the associated national reporting framework. Through this process the DUQST will be able to continue to provide feedback to the maternity, neonatal and corporate teams ensuring that there continues to be an appropriate level of independent scrutiny.

The chart below shows the reporting rates for nationally reportable incidents per 100,000 populations by CTMUHB since the implementation of the new incident reporting policy in June 2021. The fluctuation in numbers is a result of the timing of reporting to the DU.



As at 31 March 2022

The chart below shows a comparative analysis of with other NHS Wales Health Boards, showing that CTMUHB had neither high or low reporting rates for incident that meet the national reporting threshold. It should be recognised that new national policy for incident reporting has only been in place for 10 months so the data is limited at present.

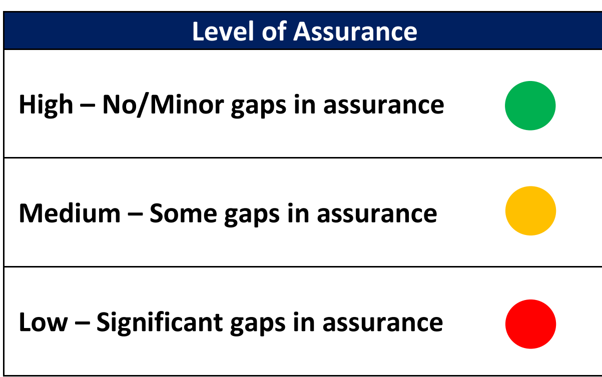


As at 31 March 2022

The initial findings of the maternity and neonatal incidents were identified in a report published by the DU in August 2021, the same report also made 7 recommendations that CTMUHB should meet in order to provide assurance that incidents are being effectively managed.

The progress made against all recommendations and levels of assurance are listed in the table below. The assurance levels are based on the assessment of evidence against the recommendations and are the DUQST assessment of assurance levels.

Assurance Key



Level of Assurance	
High – No/Minor gaps in assurance	(green)
Medium – Some gaps in assurance	(amber)
Low – Significant gaps in assurance	(red)

Table 1 **Part A - Maternity and Neonatal Services Serious Incidents Assurance Review**		
Independent Review Recommendation	**Progress Against Recommendation**	**Assurance**
RCOG & RCM Review Recommendations against Terms of Reference 3 – March 2019		
ToR 3: Review the RCA investigation process • how SIs are identified, reported and investigated with the maternity services; • how recommendations from investigations are acted upon by the maternity services; • how processes ensure sharing of learning amongst clinical staff, senior management and stakeholders and whether there is clear evidence that learning is undertaken and embedded as a result of any incident or event.	The Health Board are in the process of adopting and rolling out the new 'Once for Wales' Datix Risk Management System (incident module), which supports staff in the prompt reporting of Patient Safety Incidents. The system should be used as an opportunity to update staff knowledge and understanding of what, how and when to report incidents. Roll out is due to be completed by the end of April in line with nationally agreed timeframes. Automatic feedback functions at the point of closure should be used as one mechanism to support feedback to reports and those involved in investigations. There is evidence of good levels of action planning within the Maternity and Neonatal Service Improvement Plan, to deliver learning from Datix incidents back to staff. Assurance has been given by the Health Board, that following feedback, ongoing investigations are now discussed by MDT and if necessary include the wider Health Board departments. There has been the Introduction of DUQST led Scrutiny Panel, for incident closures submitted by the Health Board. Following the scrutiny of cases, the DUQST will either recommend, to Welsh Government, cases that meet the threshold for closure or provide feedback to the Health Board team on changes/improvements that need to be made for incidents to meet the closure threshold. The Panel consists of MDT and includes a wider range of personnel to support a more robust triangulation of assurance closure. This is good practice and a good exemplar and needs to continue.	Assurance level – **Medium** **Gaps in assurance:** Effective and timely feedback from the RLDatix system. *Feedback via the RL Datix system to those who have reported incidents will improve once CTMUHB have gone live with the new RL Datix Once for Wales Concerns Management System (OfW CMS) that will provide an automatic direct feedback capability as incidents are closed.*

	In regards to staff receiving feedback, the DUQST saw feedback given via a number of electronic cascade methods. However, there was little evidence of incident feedback via the Datix system or face to face. This resulted in staff, on the front line, feeling that timely feedback is an area for further improvement. The DUQST found established 'local escalation with Multi-Disciplinary Teams' (MDTs), which make initial assessments of Datix reported incidents on a, site based, weekly basis. These local MDTs, filter the grading of Incidents reported by Maternity and Neonatal into cases that could be managed at local levels and cases that require ongoing investigations. During that meeting, any incidents graded moderate or above would be escalated to a Health Board wide oversight panel. There has been significant progress made in how learning from incidents is shared, moving from mainly using electronic feedback systems to now also including learning events, safety summits that are open to all staff and feedback sessions to staff directly involved in incidents.	
Recommendation - 7.19 Ensure that a system for the identification, grading and investigation of Sis is embedded in practice through: • *appropriate training to key staff members,* • making investigations multidisciplinary and including external assessors *The Neonatal Deep Dive also recommends that:*	The Health board have appointed a number of lead clinical medical staff with the role and responsibility for Risk Management and Incident Management. There was good leadership, engagement and involvement of Paediatric, Neonatal, Obstetric and Anaesthetic medical leads in the incident investigations, scrutiny, improvement and learning. There was evidence of joint investigations or opinions being sought from other interdependent disciplines as necessary, this has included external neonatal involvement on occasion. The Health Board have been accessing the DUQST to seek advice on any new incidents and their appropriate reporting approach. This is positive engagement and provides an opportunity for the Maternity and Neonatal teams to seek an external perspective.	Assurance level **– High** **Gaps in assurance:** In line with the Neonatal Deep Dive recommendation RCA's will benefit from more external specialist input, for example increased external neonatology input.

The Health Board must ensure clinical incident reviews, SI reviews and PMRT/Mortality reviews are carried out as an MDT with external support from colleagues within the local NICU to provide clinical expertise and questioning. *The suggested minimal interventions for this recommendation are as follows:* • *Establish and monitor SI processes seeking additional clinical expertise when required to support local learning regarding what a good review looks like.* • *Wider Health Board engagement in governance reviews from corporate patient safety team.* • *Ensure timely feedback to staff reporting incidents and also of lessons learnt to avoid repeated incidents of harm.* • *Agreed changes in practice must be described in context to ensure staff understand the rationale and expected outcome of changes.*	All staff leading the investigation of serious incidents, including those that reach the threshold for national reporting, undergo a CTMUHB RCA training and the training package can be seen at **appendix 1**. It was identified in the early part of the intervention that staff felt they would benefit from improved support when translating the theory of the formal RCA training into practice, in response to this the CTMUHB corporate Q&S team have put in place patient safety clinics, the first of which commence in April 2022 and an incident management toolkit, that is due to launch on the 22 May as to compliment the implementation of the national RL Datix OfW CMS. In addition to the technical support for managing an RCA there is access to the current welfare support services, 'Assist Me'. The Assistant Director of Quality and safety is also currently exploring the TRiM model for supporting colleagues involved in incidents, incident management and investigation to further improve how staff are supported with resilience, a just culture and their wellbeing. The 72 serious incidents that are the focus of this assurance review have benefited from multidisciplinary approach, were appropriate, including maternity, neonatal nurses and clinicians, along with other relevant expertise such as pharmacy etc. They have also had the benefit of specialist input external to CTMHUB where appropriate. This has included the RCA processes and newly established MDT. The thematic learning from the 72 serious incidents correlate with the same themes as the neonatal deep dive findings. Therefore, the areas for focused learning and improvement are well rehearsed to effect the necessary change in policy and practice. In line with the Neonatal Deep Dive Recommendation external NICU/Neonatology expertise has been sought to provide input into neonatal incidents this is still in its infancy and more incidents will benefit from this level of input in the future.	

Recommendation	Evidence	Assurance
Recommendation – 7.20 Actively seek to remove the 'blame culture' to allow all staff to develop a willingness to report and learn from SIs.	The Health Board actively took the feedback from the DUQST on board, implementing their first Multidisciplinary learning events to promote shared learning from incident case investigations. These were observed by the DUQST and had a strong emphasis on learning and improving. There was a focus on thematic learning from a number of cluster investigations, including Maternal admissions to ITU, fallen babies and wrong administration of expressed breast milk. The benefits of aggregating the cases enabled a stronger focus on system factors that could be implemented rather than a focus on individuals. This approach is exemplar good practice and needs to be continued, as it will support a further shift in a feeling of punitive culture. Frontline staff should be rostered to attend and on a rotational basis so there is wide spread access to all frontline staff. The Health Board has also participated in the National Never event symposium sharing their learning from never events on a National platform.	Assurance level **– High** **Gaps in assurance:** Nil
Recommendation – 7.21 Improve incident reporting by: • delivering training on the use of the Datix system for all staff, • encouraging the use of the Datix system to record clinical incidents, • monitor the usage of the incident reporting system	The Health Board have actively participated in the rollout of the new Incident National Policy and Guidance. DATIX training will updated for all staff as part of the implementation of the national Once for Wales Concerns Management System (RL Datix). This new system is also more user friendly and simpler to use supporting the use of RL Datix. The DUQST has been monitoring the Services use of the Incident Reporting system, with a good range of low, medium and high level incidents. This has been supported by weekly reports of incidents at all grades, the Health Board have submitted to the Delivery Unit, for Maternity and Neonatal, Paediatrics and Gynaecology.	Assurance level **– Medium** **Gaps in assurance:** Training for all staff in the use of RL Datix. *Training for all staff will be delivered as part of the implementation of the new national system.*
Recommendation – 7.22 Actively discuss the outcomes of SI's in which individual consultants were involved in their appraisal.	The Clinical Director for Maternity has liaised with the Medical Director to address this recommendation. They noted that as the appraisal process is confidential, the appraiser will not have access to the parameters required to monitor or record the discussion. For that reason, the Health Board has amended its Serious Incident tool kit **(see appendix 1)** to include '*all those involved in an SI should reflect on incident with an appropriate person;* *· For students/doctors in training, the reflection should take place with their educational supervisor.*	Assurance level **– High** **Gaps in assurance:** Nil

	· For SAS doctors, the reflection should take place with a named educational supervisor if there is one, and the Clinical Director if not. *For consultants, the reflection should take place with the Clinical Director.'* The record of reflection, having been completed, will form part of the evidence when the Learning from Events record is completed.	
Recommendation – 7.23 Improve learning from incidents by sharing the outcomes from Serious Incidents on a regular basis and in an appropriate, regular and accessible format.	As identified in recommendation 7.20, there is progress being made in relation to shared learning, with examples that the service will share nationally with the network.	Assurance level **– High** **Gaps in assurance:** Nil
Recommendation – 7.24 Identify a clinical lead from senior medical staff within the directorate to support the current midwifery governance lead.	The Health Board have now appointed two key medical leadership staff, who are leading and engaging in the governance agenda.	Assurance level **– High** **Gaps in assurance:** Nil
NHS Wales Delivery Unit Assurance Review Recommendations – August 2021		
NHS Wales DU Recommendation 1 The Health Board undertakes a capacity assessment of Maternity and Neonatal services, to ensure there is sufficient capacity and skills to manage incidents, including incident reporting, proportionate investigations, sharing of learning, and the implementation of corrective actions. The assessment should be factored against average incident reporting numbers over the past 12 months, and in keeping with requirements of the national incident reporting Framework.	In order to ensure that there is both capacity and appropriate skill mix to effectively manage incidents in the maternity and neonatal teams have addressed this through the development of MDT incident quality assurance and closure panels that are scheduled in advance to allow clinicians to attend. In support of the incident quality assurance panels a set of Terms of Reference (**see appendix 1**) have been established to provide clarity on the role and purpose of the panels. The key purpose of which is to provide high-level scrutiny of incidents, with independence from those investigating the incident and challenge Quality Assurance. A coordinator has been provided from within the corporate Q&S team to support the activities required for incident quality assurance panels. There have been 15 panels in total and they have reviewed all 72 outstanding incidents. The panels will continue as an embedded part of the incident management process moving forward.	Assurance level **– High** **Gaps in assurance:** Nil

Recommendation 2 *The Health Board has developed a Quality Assurance Framework for Maternity and Neonatal services (see appendix 1). The Framework should support consistency in the effective governance of quality and safety matters across the clinical support groups, ensuring integration with Locality Groups and central (Corporate) functions. The Framework will clearly define accountability of the Integrated Locality Groups (ILG) and the corporate responsibilities of the Director of Midwifery and Director of Neonatal Services.*	A maternity and neonatal quality assurance risk and escalation framework has been developed (**see appendix 1**) and is to be presented to the CTMUHB Q&S committee on the 22 March 2022 for note and approval for implementation. It should be noted that the framework has been developed to meet the current CTMUHB organisation structure, including clinical service and locality groups. This structure is currently under review and early recommendations identify the need for a dedicated women and children's directorate, it is felt by the DUQST that this will be beneficial to supporting the governance and accountability structures for maternity and neonatal services.	Assurance level **– Medium** **Gaps in assurance:** The Assurance & Risk Escalation Framework is currently in the approval process. *The framework will need to be reviewed once the new CTMUHB organisation structure has been implemented.*
Recommendation 3 *The Delivery Unit continues to monitor and provide independent quality assurance to the Serious Incident closure forms until the Service is out of special measures.*	The DUQST has continued to support the CTMUHB maternity, neonatal and corporate teams since the assurance review commenced in May 2021. Support will continue once the assurance review is formally closed through current national reportable incidents process for which the DUQST provides oversight, scrutiny and feedback on incidents that meet the threshold for national reporting.	Assurance level **– High** **Gaps in assurance:** Nil
Recommendation 4 *A mentorship system is developed to support new investigators during their first investigations. Consideration should be given to the benefits of a peer support group which incorporates clinical supervision for investigator's, recognising the emotional resilience required to undertake this area of work.*	There currently an existing serious investigation toolkit (**see appendix 1**), a new toolkit in line with the new national incident reporting policy is in draft. The CTMUHB corporate Q&S team have been supporting those responsible for investigating incidents, both new and experienced investigators, throughout the assurance review process. In addition, rapid learning, feedback and support events have been provided for those involved in investigations.	Assurance level **– Medium** **Gaps in assurance:** Updated investigation toolkit is current awaiting approval from the Executive team.

	All staff involved in investigations currently are provided with access to the 'Assist Me' package of welfare and wellbeing support. Further support is planned through safety events, the development of an updated incident management toolkit (currently awaiting approval by the Executive team) and the investigation on the value of utilising the TRiM model to support those involved in investigation.	
Recommendation 5 *To support a healthy organisational reporting culture, and following the adoption of the new Once for Wales Datix Incident management module, the Health Board should mandate that the outcomes field is completed with identified learning and actions prior to the closure of incidents, so that meaningful feedback is given automatically to the reporter upon closure.*	CTMUHB is now using he feedback to reporter feature of the RLDatix system, providing feedback to the those reporting incidents on what action has been undertaken, an important feature in order to provide feedback and help encourage incident reporting. Group feedback meetings are being trialled within the maternity and neonatal services, providing a comprehensive and supportive feedback to those involved in incidents. CTMUHB are scheduled to go live with the new RL Datix Once for Wales Concerns Management, this will see training in the use of Datix for incident reporting and also make the process simpler for staff.	Assurance level **– Medium** **Gaps in assurance:** The new national RL Datix Once for Wales Concerns Management System go live is scheduled for the end of April in line with national implementation timelines.
Recommendation 6 *To support a just organisational culture around the reporting and investigation of incidents, the Health Board should ensure investigators focus learning and actions, where applicable, to a more systems analysis approach, rather than focusing findings and actions to individuals involved in incidents. A 'Just Culture' should continue to be embedded in the organisation through the existing focus on the organisations new values.*	CTMUHB have implemented a training programme for all incident investigators (**see appendix 1**), that focuses on establishing the root cause, learning and appropriate improvement actions. This is having a positive impact on the quality and focus of investigations. There has been the implementation of a new safety resource with CTMUHB, this is dedicated to promoting the importance of patient safety with an open and supportive culture. Patient safety clinics have commenced in April 2022 to provide peer support, advice and information.	Assurance level **– High** **Gaps in assurance:** Nil

Recommendation 7 The Health Board should review and update the central policy for the management and investigation of incidents to align with recently updated national incident reporting policy, and NHS Wales implementation guide published by the Delivery Unit.	CTMUHB currently have a comprehensive and approved central investigation policy. In a paper to the Q&S Committee it has identified that the current policy needs updating to meet. A new proportionate investigation toolkit with checklist has been launched to support the investigation of moderate harm incidents to ensure that they are appropriately investigated and learning identified along with serious incidents.	Assurance level **– Medium** **Gaps in assurance:** The current investigation policy requires updating in line with the new national incident reporting policy and guidelines.

2. Part B – Intervention into Board Systems and Processes for Reporting, Management and Review of Patient Safety Incidents

Overall

As with the maternity and neonatal SI assurance review the CTMUHB corporate Q&S team have engaged with the DU well over the past 12 months in relation to addressing a number of the remaining improvement actions associated with intervention.

Since summer 2018, the Quality & Safety (Q&S) team of the Delivery Unit (DU) has carried out a number of reviews to gain assurance for WG that CTMUHB have robust processes and systems in place for the management of incidents and concerns.

The findings can be reviewed in the following reports:

1. Management of Serious Incidents in Maternity Services (December 2018)
2. Management of Concerns (Learning Lessons and Managing Risk) and the Supporting Governance Arrangements (March 2019)
3. Intervention into Cwm Taf Morgannwg University Health Board systems and processes for reporting, management and review of patient safety incidents and Concerns (September 2019).
4. Intervention into Cwm Taf Morgannwg University Health Board systems and processes for reporting, management and review of patient safety incidents and Concerns – *Interim review one year on: snapshot review of Serious Incident investigations.*

Terms of reference for the targeted intervention were agreed between the DU and CTMUHB in July 2019 (**see appendix 1**).

Unfortunately, since September 2019 the intervention has suffered from a number of changes to key personnel at both the DU and CTMUHB. This along with the COVID 19 pandemic has hampered the progress of agreed improvements.

As a result, and with the DUQST commissioned by the Welsh Government IMSOP lead to conduct an assurance review on the maternity and neonatal serious incidents it was decided that the best approach to helping establish the latest position in relation to progress against the targeted intervention recommendations was for CTMUHB to conduct a self-assessment and for the DU-QST to conduct an assessment and identify any gaps in the responses to each recommendation and associated evidence.

The CTMUHB was provided the to the DU in July 2021, following a review of the responses provided in the self-assessment along with evidence provided the DU summarised its key findings and comments to the self-assessment and evidence (**see appendix 1**).

The DU-QST also used external inspection reports to help inform its understanding of progress made in relation to quality governance within CTMUHB. The Joint Audit Wales and Health Inspectorate Wales review of progress made against the recommendations made following an initial joint review of Quality Governance Arrangements at CTMUHB in November 2019. The progress review against the recommendations was completed in May 2021 (**see appendix 1**).

Table 2 Part B– Intervention into Board Systems and Processes for Reporting, Management and Review of Patient Safety Incidents		
Targeted Intervention Recommendation **(*Self-Assessment Questions*)**	**Progress made against key findings from the self-assessment** **(Focuses on the gaps in evidence/assurance identified in the self-assessment)**	**Assurance**

1. How does the Quality and Patient Safety Governance Framework clearly set out?
a. How the HB will assure itself that it is developing a safety culture
b. anticipated quality and safety outputs/outcomes, and how and when these will be measured
c. what quality & safety information, must be reported to the Board as routine
d. when and how to escalate quality & safety issues within the Board and Committee structures
e. what measures the HB will use to assure itself that the Framework is working?
	Review of Quality & Safety Committee and Board reports
	Q&A report to Committee are well written, clear and cover the relevant quality and safety indicators and assurance on matters of importance for quality and safety at ILG and corporate levels generally, however they lacked the following in relation to the current targeted intervention for maternity services:
	- Given the ILG accepted responsibility for maternity on 1st May 2021 it is expected that this would be reflected in the ILG paper
	  ○ **action** that ILG quality and safety papers report on maternity/neonatal special measures and incident progress as a minimum.
	Response - Update reports of progress against the maternity and neonatal serious incidents assurance review recommendations (including the RCOG/RCM ToR3 recommendations) have been presented to the Quality & Safety Committee.
	- The corporate risk register has no reference to maternity special measures
	  ○ **action** to arrange a risk assessment and entry
	Response - A risk assessment has been undertaken and risk is now showing on the detailed risk register as risk 4789, Board papers reviewed to identify this.
	- The corporate reporting of maternity services to board/quality and safety committee is not written strongly enough and doesn't outline any risks such as open incidents, capacity to investigate,
		Assurance level **– High** (green)
		Gaps in assurance:
		Nil

	thematic learning and their cross reference to RCOG recommendations **Response** - **Update reports reflecting the above are provided to the Quality & Safety committee and Board, via the Quality & Safety committee highlight report. CSG's are represented on the ILG governance committees with the ILG governance committees providing highlight reports to the Quality and safety Board committee, providing a governance framework for the flow of information through the governance structure.** **The DU have also seen evidence of effective Quality and Safety reporting as part of regular assurance surveillance at quality and Safety committee and Board level.**	
2. How has the HB strengthened its approach to: a. integration of inter-related areas such as concerns, safeguarding, H&S, audit, quality improvement and risk management? b. triangulation of information from multiple sources to identify areas of risk c. provision of qualitative and narrative information which adds intelligence to the information already being provided at all levels of the HB. At a minimum this must include information about key concerns; trends/themes identified; as well as outcomes and learning?	We will request the following; • Organogram **Response - An organogram identifies the corporate governance structure.** • Board Quality and safety committee reports/ minutes **Response – Quality and safety committee papers show good reporting of quality and safety matters from across the organisation, including:** • **Highlight reports from sub-committees and ILG's** • **Quality dashboards** • **Risks** • **Progress reports on key quality and safety issues, such as the maternity and neonatal SI assurance review and Neonatal deep dive report.** **The DU regularly review the quality and safety committee and board papers as part of regular assurance surveillance.**	Assurance level **– High** **Gaps in assurance:** **Nil**
3. How has the HB clarified expectations, roles and responsibilities, and required skills for	Additional information/cooperate documents required for review • See organograms	Assurance level **– High**

management of concerns at both the Corporate and Directorate level? a. How has this been clearly articulated to Directorates (who are responsible for determining local resource levels) so that the HB's expectations of how quality and safety resource should be obtained and managed are clear and unambiguous?	**Response - An organogram identifies the corporate governance structure.** • Relationship between cooperate and maternity and the management of quality and safety? **Response – The DU-QST have witnessed significant improvement of the collaboration between the maternity, neonatal and the corporate Q&S team, this has led to significant improvements in the management of incidents and concerns.** • The DU has reviewed the Standard Operating Procedure that outlines the governance requirements within ILG for incident scrutiny.	**Gaps in assurance:**
4. How has the HB assured itself that there is sufficient resource allocated to quality and safety to facilitate a robust multi-disciplinary approach to risk management and management of concerns?	See Central Team and IGL organograms. – corporate **Response - Organograms provided show the ILG structure that includes:** **ILG Director** **Nurse Director** **Head of Quality and Patient Safety** **The ILG governance meeting also provide an MDT platform to review local risk, incidents and concerns that feed through from the CSG's.** **The CSG structures differ slightly depending on the clinical specialty, however there is CSG and Corporate Quality & Safety team representation at ILG governance committees.**	Assurance level **– Medium** **Gaps in assurance:** The ILG structure is planned to change and the future governance of maternity/neonatal services will need to be re-defined.
5. Has the HB reviewed its end to end processes for management and investigation of incidents,	The assurance review covers this point – CLOSED.	N/A

including how learning is used to improve safety, and how has it ensured that: a. a recognised systems-based methodology incorporating human factors which focuses on system learning is consistently applied including to non-SI incidents where appropriate		
6. Has the HB reviewed its end to end processes for management and investigation of incidents, including how learning is used to improve safety, and how has it ensured that: a. a recognised systems-based methodology incorporating human factors which focuses on system learning is consistently applied including to non-SI incidents where appropriate b. the HB can be assured that learning from investigations results in the completion of action plans and generation of required changes to improve patient safety?	The assurance review covers this point – CLOSED.	N/A
7. Has the HB considered review of the in-house training on incident management by an L&D professional to ensure that learning objectives are clear?	The assurance review covers this point – CLOSED.	N/A
8. How is the HB supporting staff delivering internal training e.g. with Train the Trainer training?	The assurance review covers this point – CLOSED	N/A

9. Has the HB process mapped all elements of how incidents should be managed, and how has this been used to update the supporting policy suite to ensure that organisational expectations are clearly articulated?	The assurance review covers this point – CLOSED.	N/A
10. How has the HB ensured that expectations around generation, delivery and monitoring of action plans generated from concerns are clearly articulated to the Directorate staff involved in these processes?	Request a Sample of cooperate action plans. Request a ward improvement plan for the central teams. **Action – Whilst action plans can be further improved, particularly in relation to being SMART, action plans are monitored and where appropriate rolled up into themes in order to manage the same improvement actions across a number of concerns. Feedback sessions are provided to staff involved in incidents and learning events organised focused on themes identified. This monitoring and feedback process has been particularly well developed in the maternity service with the neonatal service following suit as a result of the SI assurance review. The corporate Quality and Safety team are now sharing this approach as best practice.**	Assurance level **– Medium** **Gaps in assurance:** The process adopted by the maternity and neonatal services is progressing across other clinical service groups.
11. How has the HB linked action plans at a strategic HB level to inform wider learning, maximise improvement on common themes and be aligned to service improvement, to make better use of limited resources?	Request ToR's, Agenda and Minutes from the SL&LF. See the Weekly Tuesday Newsletters. **Action – As identified earlier there is improved service to board flow of information, including that related to risk and associated improvement plans. The Listening and Learning Forum was established in February 2021 and is positively contributing to shared learning across CTMUHB.**	Assurance level **– High** **Gaps in assurance:** A Listening & Learning Framework that will further support shared learning is still in development.
12. How has the HB gained assurance on the delivery of action plans to generate improvements to patient safety?	See the safety and Effectiveness report. AMAT	Assurance level **– Medium**

	Action – Patient safety monitoring metrics are monitored and reviewed at all governance levels CSG's through to Board. This has been very visible as part of the service to board flow of information the DU has seen as part of its regular assurance surveillance. CTMUHB central Quality and Safety team have also engaged with the CTMUHB Clinical Audit department to expand the use of the AMAT system that is used to monitor clinical effectiveness and compliance has been established for maternity, the Corporate Q&S team are now working to expand this approach across the HB.	**Gaps in assurance:** The AMAT system is yet to be expanded across the HB.
13. As part of the Board's review of its Assurance Framework and Risk Register, how are all sources of risk intelligence being integrated to give more insight into the risks facing the organisation?	The May 2021 joint Audit Wales and Healthcare Inspectorate Wales review of progress made against the recommendations from the initial review of Quality Governance and Risk Management arrangements (Nov 2019) identified the following progress: *Arrangements for the identification and management of risk have been strengthened. There has been significant work undertaken throughout the Health Board to implement the new risk management strategy, and this is now in place and operating. Processes for managing, identifying, and mitigating risk have improved. Operationally, ILGs have made an effective contribution to this by reviewing risks in their areas to ensure that an accurate and up to date picture of risks is now being presented. Despite early progress, further work is needed to ensure that the highest rated CSG risks are appropriately escalated to the ILG risk registers – Joint AW/HIW review of progress report May 2021* **Since the publication of the Joint AW/HIW review of progress the DU have seen the good flow of risk information through the CTMUHB governance structures as part of regular assurance surveillance. However, it is not able to see the progress of high CSG risks being appropriately escalated to ILG. It is also noted from Board papers that the Board Assurance Framework (BAF) is under development. It is not**	Assurance level **– Medium** **Gaps in assurance:** There needs to be clear evidence of the escalation of high risks from the CTM's to the ILG's. The Board Assurance Framework is currently under review and further development to help. The improved BAF needs to be fully implemented and bedded in to provide assurance that the Board are focused on strategic risks and fully aware of controls and assurances.

	evident that the Board are focused on strategic risks, control and assurances, although the new improved BAF should improve this.	
14. What is the HB's approach to improving its ward-to-Board risk management system?	See above from the joint AW/HIW review of progress report. **information through the CTMUHB governance structures as part of regular assurance surveillance. Since the publication of the Joint AW/HIW review of progress the DU have seen the good flow of risk. However, it is not able to see the progress of high CSG risks being appropriately escalated to ILG. It is also noted from Board papers that the Board Assurance Framework (BAF) is under development. It is not evident that the Board are focused on strategic risks, control and assurances, although the new improved BAF should improve this.**	Assurance level **– Medium** **Gaps in assurance:** There needs to be clear evidence of the escalation of high risks from the CTM's to the ILG's. The Board Assurance Framework is currently under review and further development to help. The improved BAF needs to be fully implemented and bedded in to provide assurance that the Board are focused on strategic risks and fully aware of controls and assurances.
15. How has the HB ensured that capacity and capability exist in the organisation to deliver on an integrated approach to risk management?	The May 2021 joint Audit Wales and Healthcare Inspectorate Wales review of progress made against the recommendations from the initial review of Quality Governance and Risk Management arrangements (Nov 2020) identified the following progress: *Newly appointed Nurse Directors are in place for each of the three ILGs, and they are responsible for supporting quality governance, which is a shared responsibility across the three ILG senior leaders. In addition, each ILG also has a Head of Quality and Safety in place to support the quality governance agenda. Their role is to support the work of quality and patient safety within the ILGs, linking with the central Patient Care and Safety Team and the Assistant Director for Quality, Safety and Safeguarding - Joint AW/HIW review of progress report May 2021.*	Assurance level **– High** **Gaps in assurance:** Nil

16. How has the HB ensured that systems and processes for organisational learning incorporate clear lines of accountability and management arrangements between the Board, corporate support services, directorates, clinical services and other NHS organisations?	The May 2021 joint Audit Wales and Healthcare Inspectorate Wales (AW/HIW) review of progress made against the recommendations from the initial review of Quality Governance and Risk Management arrangements (Nov 2019) identified the following progress: *Positive steps have been taken by the Health Board to improve organisational culture and learning. The Health Board launched its Values and Behaviours Framework in October 2020. Whilst it is too early to assess the impact of this framework, there are encouraging signs from its implementation and roll out. The framework was co-produced with a range of stakeholders including staff, stakeholders, and the local community. Whilst plans are in place to strengthen the Health Board's processes for organisational learning e.g., the establishment of the Shared Listening and Learning forum, this is an area that will require continued focus and attention to ensure that improvement is sustained - Joint AW/HIW review of progress report May 2021.*	Assurance level **– Medium** **Gaps in assurance:** The CTMUHB Shared Listening and Learning Forum is newly established and will need to bed into practice.
17. How has the HB ensured that reports generated from the risk management system focus at least equally on learning/improvement on par with performance, and be disseminated as widely as possible to support organisational learning?	The May 2021 joint AW/HIW review of progress made against the recommendations from the initial review of Quality Governance and Risk Management arrangements (Nov 2019) identified the following progress: *Positive steps have been taken by the Health Board to improve organisational culture and learning. The Health Board launched its Values and Behaviours Framework in October 2020. Whilst it is too early to assess the impact of this framework, there are encouraging signs from its implementation and roll out. The framework was co-produced with a range of stakeholders including staff, stakeholders, and the local community. Whilst plans are in place to strengthen the Health Board's processes for organisational learning e.g., the establishment of the Shared Listening and Learning forum, this is an area that will require continued focus and attention to ensure that improvement is sustained - Joint AW/HIW review of progress report May 2021.*	Assurance level **– Medium** **Gaps in assurance:** The CTMUHB Shared Listening and Learning Forum has only been newly established and will need to bed into practice.

18. How has the HB ensured that incident reports of all levels of harm are rapidly reviewed to identify risk to the patient involved or to other patients?	The assurance review covers this point – CLOSED	N/A
19. How has the HB built on the good practices observed in the initial SI meeting process, and have these been rolled out across the organisation?	The assurance review covers this point – CLOSED.	N/A
20. Has the HB undertaken an assurance review of its Being Open processes to ensure that the expected processes are systematically being followed for all appropriate concerns?	Listening and Learning Cooperate group – ToR's, agendas, minutes. **Quality Assurance panels have been established and embedded as normal practice in the maternity and neonatal teams, this is now being shared as best practice across the Health Board by the Corporate Quality and safety team.** **The Listening and Learning Forum was established in February 2021 and is positively contributing to shared learning across CTMUHB.**	Assurance level **– Medium** Gaps in assurance: Quality Assurance panels not embedded across the Health Board**.**

RECOMMENDATIONS

Part A - Maternity and Neonatal Services Serious Incidents Assurance Review

Whilst CTMUHB have further improvements to make in relation to the recommendations of the RCOG/RCM recommendations and further recommendations of the NHS Wales DU assurance report it should be recognised that significant improvements and progress has been made to the quality of managing serious incidents with the maternity and neonatal services.

The maternity, neonatal and corporate Q&S teams are also aware that there are a number of improvements still to be completed, legacy actions, it is recommended that these actions are captured in the CTMUHB Milestone Plan so that progress against achieving them can be monitored through the existing governance and oversight arrangements in place for the long term maternity improvement plan.

As a result of the significant progress made to date and clear understanding of the continuous improvement requirements and how they need to be managed moving forward within CTMUHB, the levels of assurance achieved against all recommendations the DU recommends that the 72 serious incident progress to closure and the formal assurance review by closed.

Part B – Intervention into Board Systems and Processes for Reporting, Management and Review of Patient Safety Incidents

Through the self-assessment along with supporting evidence the review of the assessment provided by the DU-QST along with the progress made to quality governance identified in the May 2021 joint Audit Wales and Health Inspectorate Wales (AW/HIW) review of progress against the recommendations of their original review into Quality Governance arrangements at CTMUHB, conducted in November 2019, the DU feels that there are now appropriate levels of assurance that significant improvements have been made to quality and safety governance, accepting, as also identified in the AW/HIW progress review, CTMUHB are on an improvement journey with further improvements to be made.

As a result, it I recommended that the targeted intervention into the Board Systems and Processes for Reporting, Management and Review of Patient Safety Incidents be closed and that the DU continue to monitor CTMUHB's progress as part of it standard quality and safety assurance monitoring process.

CONCLUSION

There were a number of areas at risk, that the Maternity and Neonatal services and more broadly in the governance of patient safety incidents required intervention and support from the DU-QST. During our time in supporting the Health Board, they have demonstrated strong leadership, engagement and a determination to put things right. In particular, the Central Team involvement has had a significant impact on improving the quality of incident management supporting the Maternity and Neonatal services and supporting the governance of quality at service and ILG levels. This service

to board approach has been key to achieving the pace of change to date. There is positive multidisciplinary leadership and engagement team working and a shared accountability for of patient safety. The Health Board and its Maternity and Neonatal services are well placed to build on the actions and the improvements identified in this report and mature their approach to that of exemplar status.

APPENDICES

Appendix 1 –references

Title	Document
Terms of Reference for the Maternity and Neonatal Serious Incidents Quality Assurance Review	2021-06-15 - NHS DU Cwm Taf Morgai
The Health Board's RCA Training Programme	20210625 - Root Cause Analysis Trainir
The Health Board's SI Tool Kit	2021-08-05 Serious Incident Review Toolk
Maternity & Neonatal Closure and Assurance Panel Terms of Reference	M NN Assurance Closure Panels ToR V:
CTMUHB Maternity & Neonates Assurance, Risk and Escalation Framework	Maternity Neonates Assurance Framework
Systems and Processes for Reporting, Management and Review of Patient Safety Incidents	DU ToR July 2019 Greg and Jeremy sigr
CTMUHB Targeted intervention and Maternity/Neonatal self-assessment	20210707 - CTM Self Assessment - modifie
Joint AW/HIW Quality Governance Arrangements at CTMUHB Review of progress against recommendations May 2021	Cwm-Taf-Joint-review-eng_0.pdf

Appendix 2 – Acknowledgements

The Delivery and Support Unit would like to thank the staff at Cwm Taf Morgannwg University Health Board for their support with the Maternity and Neonatal Services Assurance Review.